AMENDMENT

IN THE CLAIMS

The following Listing of Claims will replace all prior versions, and listings, of claims in the application.

LISTING OF CLAIMS

1. (Previously Presented) A system for clinical research data management for a plurality of users, comprising:

a computer system operable to service user requests and provide users with information responsive to the user requests; and

a database coupled to the computer system and populated with study information of one or more studies which includes user data and study data, the study information being accessible from the database for obtaining the responsive information, the study data including candidate data, specimen data, event data, and at least one dataset defined using metadata, wherein the database is operable to store user data and study data,

wherein the study data includes candidate data associated with candidate subjects for a clinical data study, specimen data representing specimens associated with the candidate subjects, event data for tracking events associated with medical treatment of candidate subjects, and at least one dataset associated with at least one of the candidate subjects, wherein the dataset is defined using metadata, and

wherein the user data includes a plurality of roles defining data access rights associated with the users, wherein the roles include a data monitor role entitling a user to review specified data, an enroller role entitling a user to enroll candidate subjects in a study, a data editor role entitling a user to add and edit data, a data study administrator role entitling a user to assign roles to users, and a system administrator role entitling a user to manage user access to the system for specified roles; and

wherein the computer system is operable to send and receive electronic messages between at least two users and to limit communication of electronic messages between users to those users having a specific role in connection with a specific study.

2. (Previously Presented) The system of **claim 1** wherein the event data includes data of events that are scheduled events, unscheduled events, or both.

Claims 3 – 7 (Canceled)

8. (Previously Presented) The system of **claim 1**, wherein the role defines data access rights granted at a dataset definition level, data item definition level, or both.

Claims 9 – 10 (Canceled)

11. (Previously Presented) The system of **claim 1**, wherein the database is operable to identify at least a portion of the user data as privacy data and wherein the role defines a user's capability to view privacy data.

12. (Previously Presented) The system of **claim 1**,

wherein the database includes at least one display form associated with the dataset, and

wherein the display form is defined using metadata.

13. (Previously Presented) The system of **claim 1**,

wherein the database includes at least two display forms associated with the dataset; and

wherein the display forms are defined using metadata.

14. (Previously Presented) The system of **claim 13**, wherein a first display form is formatted to render the dataset on a first display device, and a second display form is formatted to render the dataset on a second display device.

15. (Previously Presented) The system of **claim 13**, wherein a first display form is formatted to render the dataset in a first language, and a second display form is formatted to render the dataset in a second language.

16. (Previously Presented) The system of **claim 1**, wherein the database stores an audit record of data access including information relating to the data accessed, user, date and time.

17. (Previously Presented) The system of **claim 1**, wherein at least a portion of the user data or study data is stored in the database in an encrypted format.

18. (Currently Amended) A method for clinical research data management for a plurality of users, comprising:

defining in a computer system at least one dataset using metadata;

storing user data and study data in a database coupled to the computer system,

wherein the study data includes candidate data representing candidate subjects for a clinical data study, specimen data representing specimens associated with the candidate subjects, event data for tracking events associated with medical treatment of candidate subjects, and the at least one dataset; and

wherein the user data includes a plurality of roles defining data access rights associated with the users, wherein the roles include a data monitor role entitling a user to review specified data, an enroller role entitling a user to enroll candidate subjects in a study, a data editor role entitling a user to add and edit data, a data study administrator role entitling a user to assign roles to users, and a system administrator role entitling a user to [[manager]] <u>manage</u> user access to the system for specified roles; and

wherein the computer system is operable to send and receive electronic messages between at least two users and to limit communication of electronic messages between users having a specific role in connection with a specific study.

19. (Previously Presented) The method of **claim 18**, wherein the event data includes data of events that are scheduled events, unscheduled events, or both.

Claims 20 - 22 (Canceled)

23. (Previously Presented) The method of **claim 18**, wherein the user data includes at least one role associated with each user.

24. Canceled.

25. (Previously Presented) The method of **claim 18**, wherein the role defines data access rights granted at a dataset definition level, data item definition level, or both.

Claims 26 – 27 (Canceled)

28. (Previously Presented) The method of **claim 23**,

wherein the database is operable to identify at least a portion of the user data as privacy data, and wherein the role defines a user's capability to view privacy data.

29. (Previously Presented) The method of **claim 18**,

wherein the database includes at least one display form associated with the dataset, and wherein the display form is defined using metadata.

30. (Previously Presented) The method of **claim 18**,

wherein the database includes at least two display forms associated with the dataset, and wherein the display forms are defined using metadata.

31. (Previously Presented) The method of **claim 18**, wherein a first display form is formatted to render the dataset on a first display device, and a second display form is formatted to render the dataset on a second display device.

32. (Previously Presented) The method of **claim 18**, wherein a first display form is formatted to render the dataset in a first language, and a second display form is formatted to render the dataset in a second language.

33. (Previously Presented) The method of **claim 18**, wherein the database stores an audit record of data access including information relating to the data accessed, user, date and time.

34. (Previously Presented) A system for clinical research data management for a plurality of users, comprising:

a computer system operable to service user requests and provide users with information responsive to the user requests; and

a database coupled to the computer system, wherein the database is operable to store user data and study data relating to a plurality of studies,

wherein study data includes candidate data representing candidate subjects for a clinical data study, specimen data representing specimens associated with the candidate subjects, event data for tracking events associated with medical treatment of candidate subjects, and at least one dataset, and

wherein user data includes at least one role associated with each user, and wherein the role defines data access rights granted at a dataset definition level, data item definition level, or both; and

wherein the computer system is operable to limit communication of electronic messages between users having a specific role in connection with a specific study.

35. (Previously Presented) A system for clinical research data management for a plurality of users, comprising:

a computer system operable to service user requests and provide users with information responsive to the user requests, and

a database coupled to the computer system, wherein the database is operable to store user data and study data relating to a plurality of studies,

wherein study data includes candidate data representing candidate subjects for a clinical data study, specimen data representing specimens associated with the candidate subjects, event data for tracking events associated with medical treatment of candidate subjects and at least one dataset,

wherein the user data includes a plurality of roles defining data access rights associated with the users, wherein the roles include a data monitor role entitling a user to review specified data, an enroller role entitling a user to enroll candidate subjects in a study, a data editor role entitling a user to add and edit data, a data study administrator role entitling a user to assign roles to users, and a system administrator role entitling a user to manager user access to the system for specified roles, and wherein user data includes at least one role associated with each user; and

wherein the computer system is operable to limit communication of electronic messages between users to those users having a specific role in connection with a specific study.

36. (Previously Presented) A system for clinical research data management for a plurality of users, comprising:

means for servicing user requests and providing users with information responsive to the user requests, the servicing means being operative to deliver messages between users; and

a database for storing user data and study data,

wherein the study data includes candidate data representing candidate subjects for a clinical data study, specimen data representing specimens associated with the candidate subjects, event data for tracking events associated with medical treatment of candidate subjects and at least one dataset, wherein the dataset is defined using metadata, and

wherein the user data includes a plurality of roles defining data access rights associated with the users, wherein the roles include a data monitor role entitling a user to review specified data, an enroller role entitling a user to enroll candidate subjects in a study, a data editor role entitling a user to

add and edit data, a data study administrator role entitling a user to assign roles to users, and a system administrator role entitling a user to manager user access to the system for specified roles; and

wherein the servicing means is operable to limit communication of electronic messages between users having a specific role in connection with a specific study.

37. (Previously Presented) A system for clinical research data management for administering a plurality of studies, comprising:

a computer system operable to service user requests and provide users with information responsive to the user requests;

a database with a flexible database structure that facilitates the study definition process for various studies;

presentation creation means operable to provide users with dynamic information;

application control and navigation means operable to service user requests; and

data access means operable to access information that resides in the database, the database being operable to store user data and study data,

wherein the study data includes candidate data representing candidate subjects for a clinical data study, specimen data representing specimens associated with the candidate subjects, event data for tracking events associated with medical treatment of candidate subjects and at least one dataset, wherein the dataset is defined using metadata, and

wherein the user data includes a plurality of roles defining data access rights associated with the users, wherein the roles include a data monitor role entitling a user to review specified data, an enroller role entitling a user to enroll candidate subjects in a study, a data editor role entitling a user to add and edit data, a data study administrator role entitling a user to assign roles to users, and a system administrator role entitling a user to manager user access to the system for specified roles; and

wherein the computer system is operable to limit communication of electronic messages between users having a specific role in connection with a specific study.

38. (Previously Presented) The system of **claim 37** further comprising application and data security means operable to limit users access to information in the system database.

39. (Previously Presented) A system as in **claim 1**, wherein the database has tables with fields associated with one or more of dataset definitions, dataset storage, dataset display, data item definitions, capabilities and roles, and events.

40. (Previously Presented) A method as in **claim 18**, wherein the database has tables with fields associated with one or more of dataset definitions, dataset storage, dataset display, data item definitions, capabilities and roles, and events.

41. (Previously Presented) A system as in **claim 34**, wherein the database has tables with fields associated with one or more of dataset definitions, dataset storage, dataset display, data item definitions, capabilities and roles, and events.

42. (Previously Presented) A system as in **claim 35**, wherein the database has tables with fields associated with one or more of dataset definitions, dataset storage, dataset display, data item definitions, capabilities and roles, and events.

43. (Previously Presented) A system as in **claim 36**, wherein the database has tables with fields associated with one or more of dataset definitions, dataset storage, dataset display, data item definitions, capabilities and roles, and events.

44. (Previously Presented) A method as in **claim 40**, wherein each of the events relates to an occurrence in time of an interaction with a study subject or patient for which the at least one dataset is collected.

45. (Previously Presented) A method as in **claim 40**, wherein an event is an initial visit, a surgery, or a follow up visit or treatment.

46. (Previously Presented) A method as in **claim 40**, further comprising tracking the events,

wherein each of the events is either scheduled or unscheduled such that, if scheduled, the events are predefined, and

wherein each of the events has a status associated therewith for tracking progress.

47. (Previously Presented) A system for clinical research data management, comprising:

a multi-tiered computer application including:

a client tier having presentation, presentation logic and user interface portions,

a middle tier including application control, business logic and data access portions, and

a data tier including a database and database management portion, wherein the database is configured for storing user data and study data,

wherein the study data includes candidate data associated with candidate subjects for a clinical data study, specimen data representing specimens associated with the candidate subjects, event data for tracking events associated with medical treatment of candidate subjects and at least one dataset, wherein the dataset is defined using metadata, and

wherein the user data includes a plurality of roles defining data access rights associated with the users, wherein the roles include a data monitor role entitling a user to review specified data, an enroller role entitling a user to enroll candidate subjects in a study, a data editor role entitling a user to add and edit data, a data study administrator role entitling a user to assign roles to users, and a system administrator role entitling a user to manager user access to the system for specified roles, and

wherein the computer application is operable to limit communication of electronic messages between users having a specific role in connection with a specific study; and

a channel for communicating data including a data network, wherein the client tier, middle tier and data tire are linked via the channel and enabling access and interaction for clinical research by geographically disparate users.

48. (Previously Presented) A method in a computerized system for clinical research data management, comprising:

defining roles for a clinical study and assigning respective ones of the roles to users of the system for clinical research data management;

managing role-based authentication and authorization, wherein a role has capabilities commensurate therewith;

defining one or more datasets for the clinical study using metadata;

defining a schedule of events for the clinical study, wherein an event has a status associated therewith;

storing the datasets in a database within the system for clinical research data management, the database being configured for maintaining clinical study data including user information, roles, capabilities, candidate data associated with candidate subjects for the clinical study, specimen data representing specimens associated with the candidate subjects, and event data for tracking events associated with medical treatment of candidate subjects;

imposing role-based restrictions on user access to the clinical study data and on communications between users having a specific role in connection with a specific study, wherein the roles include a data

monitor role entitling a user to review specified data, an enroller role entitling a user to enroll candidate subjects in a study, a data editor role entitling a user to add and edit data, a data study administrator role entitling a user to assign roles to users, and a system administrator role entitling a user to manager user access to the system for specified roles;

maintaining the status of the events by tracking their occurrence and, thereby, monitoring progress of the clinical study.

49. (Previously Presented) A method as in **claim 48**, wherein imposing the restrictions on access includes maintaining an audit trail that records users' access information.

50. (Previously Presented) A method as in **claim 49**, wherein the access information includes user's identity, time of access, type of access and level of access.

51. (Previously Presented) A method as in **claim 50**, wherein a dataset includes data items, and wherein the level of access is a dataset level, data item level, or both.

52. Canceled.

53. (Previously Presented) A method as in **claim 48**, wherein each capability maps to a functional portion of the system for clinical research data management.

54. (Previously Presented) A method as in **claim 53**, wherein the functional portions include one or more of backup database, create study, deploy study, close study, open enrollment, close enrollment, define business rules, enroll subject, disenroll subject, view enrollee, export enrollee list, create profile, disable profile, assign role, disable role, export collaborator list, delete user, approve dataset, ,retract approval, view data, edit dataset, add dataset, suspend edit capabilities, reinstate edit capabilities, export dataset.

55. (Previously Presented) A method as in **claim 48**, further comprising deploying for the clinical study one or more functional elements of the system for clinical research data management including login, candidate registration, specimen registration, study administration, data monitoring, data administration, data editing, and communication.

56. (Previously Presented) A system for clinical research data management for a plurality of users, comprising:

a computer system operable to service user requests and provide users with information responsive to the user requests; and

a database coupled to the computer system, wherein the database is operable to store user data and study data relating to a plurality of studies,

wherein study data includes candidate data representing candidate subjects for a clinical data study, specimen data representing specimens associated with the candidate subjects, event data for tracking events associated with medical treatment of candidate subjects, and at least one dataset, and

wherein user data includes at least one role associated with each user; and

wherein the computer system is operable to send and receive electronic messages between at least two users and to limit communication of electronic messages between users to those users having a specific role in connection with a specific study.

57. (Previously Presented) A system for clinical research data management as recited in **claim 56**, wherein the roles include

a data monitor role entitling a user to review specified data,

an enroller role entitling a user to enroll candidate subjects in a study,

a data editor role entitling a user to add and edit data,

a data study administrator role entitling a user to assign roles to users, and

a system administrator role entitling a user to manager user access to the system for specified roles.